## **Quarter 2 HCPCS Update**

Effective Dates of January 1st, February 9th, and April 1st 2021

## **Quarter 2 Code Additions**

## Chemotherapy

Effective for dates of service on or after April 1, 2021, the following chemotherapy codes have special billing policy:

J9037, J9349, Q2053

#### J9037

HCPCS code J9037 is indicated for the treatment of relapsed or refractory multiple myeloma in patients 18 years of age and older who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor and an immunomodulatory agent.

Frequency of billing = 2.5 mg/kg once every 21 days.

J9037 is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Blenrep<sup>®</sup> REMS because of the risks of ocular toxicity.

## Notable requirements of the Blenrep® REMS include the following:

- Prescribers must be certified with the program by enrolling and completing training in the Blenrep REMS.
- Prescribers must counsel patients receiving belantamab mafodotin-blmf about the risk of ocular toxicity and the need for ophthalmic examinations prior to each dose.
- Patients must be enrolled in the Blenrep REMS and comply with monitoring.
- Healthcare facilities must be certified with the program and verify that patients are authorized to receive belantamab mafodotin-blmf.
- Wholesalers and distributers must only distribute belantamab mafodotin-blmf to certified healthcare facilities.

Further information is available at http://www.blenreprems.com/ and 1-855-209-9188.

Modifiers SA, UD, U7 and 99 are allowed.

#### J9349

HCPCS code J9349 is indicated for the treatment of patients in combination with lenalidomide for the treatment of patients 18 years of age and older with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma and who are not eligible for autologous stem cell transplant (ASCT).

Frequency of billing = 12 mg/kg according to the following dosing schedule:

• Cycle 1: Days 1, 4, 8, 15 and 22 of the 28-day cycle

- Cycles 2 and 3: Days 1, 8, 15 and 22 of each 28-day cycle
- Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include clinical documentation that demonstrates all of the following:

- Must be used for FDA-approved indications and dosing regiments
- Patient must be 18 years of age or older
- Patient must have a diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma
  - Patient has relapsed and/or refractory disease
  - Patient has at least one bidimensional measurable disease site
- Patient has received at least one but no more than three previous systemic regimens for the treatment of DLBCL. A CD20 targeted therapy (for example, rituximab) must have been included in one therapy line
- Patients was not eligible for autologous stem cell transplant (ASCT)
- Patient has not received an allogeneic stem cell transplant or autologous stem cell transplant within the prior 3 months of therapy
- Patient was not previously treated with CD19 targeted therapy (for example, axicabtagene, tisagenlecleucel, etc.)
- Patient has not received prior therapy with immunomodulatory imide (IMiDs) agents (for example, lenalidomide)
- Patient does not have a history of positive hepatitis B and/or hepatitis C serology, or known seropositivity for HIV
- Patient has not received a live vaccine or required parenteral antimicrobial therapy for an active infection within 14 days prior to first dose
- Patient does not have central nervous system (CNS) lymphoma involvement
- Patient is using Monjovi:
  - In combination with lenalidomide for a maximum of 12 cycles of chemotherapy without disease progression or unacceptable toxicity; or
  - As monotherapy until disease progression or unacceptable toxicity after previously completing 12 cycles in combination with lenalidomide without disease progression/unacceptable toxicity.

Initial authorization is for six months

#### Reauthorization

- Patient continues to meet initial approval criteria.
- Patient has absence of unacceptable toxicity from the drug such as severe infusion reactions, severe thrombocytopenia, severe neutropenia, severe infection, etc.

 Patient has a positive clinical response evidenced by stabilization of disease or decrease in size of tumor or tumor spread.

Reauthorization is for 12 months

Modifiers SA, UD, U7 and 99 are allowed.

#### Q2053

HCPCS code Q2053 is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of patients 18 years of age and older with relapsed or refractory mantle cell lymphoma (MCL) and has a frequency of once in a lifetime.

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include clinical documentation that demonstrates all of the following:

- Must be used for FDA-approved indications and dosages
- Must be administered in a health care facility registered with the Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program
- Patient must be 18 years of age or older
- Patient must have a diagnosis of relapsed or refractory mantle cell lymphoma (MCL)
- Patient previously received anthracycline or bendamustine-containing chemotherapy, an anti-CD20 antibody (for example, rituximab) and a Bruton tyrosine kinase inhibitor (BTKi) (for example, acalabrutinib, ibrutinib, zanubrutinib)
- Patient had disease progression after their last regimen or refractory disease to their most recent therapy
- Patient must have adequate bone marrow, cardiac, pulmonary, renal and organ functions
- Patients does not have the following:
  - Active or serious infections
  - Prior allogeneic hematopoietic stem cell transplant (HSCT)
  - Detectable cerebrospinal fluid malignant cells or brain metastases
  - History of central nervous system (CNS) lymphoma or CNS disorders
- TECARTUS is not prescribed concurrently with other CAR T-cell immunotherapy (for example, Kymriah or YESCARTA)

Initial authorization is for three months (one dose only)

#### Reauthorization

Reauthorization is not approvable.

#### **REMS**

TECARTUS is available only through a restricted program under a Risk Evaluation and

Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program. This is due to Cytokine Release Syndrome and neurologic toxicities. TECARTUS must be administered in a certified health care facility.

## **Billing**

HCPCS code Q2053, is billable for up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose.

Providers are to take the following steps when submitting claims for TECARTUS:

- Submit and receive back an approved TAR/Service Authorization Request (SAR)
- Completion of claim forms:
  - Outpatient claims may be billed by paper claim using CMS-1500 or electronically using ASC X12N 837P v.5010.
  - Providers must submit one (1) service line on the TAR/SAR request and enter "4" in the Units box.
  - On the 837P or CMS-1500 claim form, provider must submit one claim line to represent one (1) service.
- Claims submitted with more than one claim line will be denied
- Provider must submit an invoice for reimbursement.
- This process will ensure that the total reimbursement paid for the quantity of four (4) is no more than the paid price on the provider submitted invoice.
- TECARTUS must be billed on its own with no other drug or biological.
- For instructions regarding physician claim form completion, refer to the Medi-Cal website, forms section for completion of 837P and *CMS-1500* claim forms.

Modifiers UD and 99 are allowed.

#### **Immunizations**

Effective for dates of services on or after February 9, 2021, the following COVID-19 monoclonal antibody codes have special billing policy:

#### M0245, Q0245

Bamlanivimab and etesevimab with HCPCS codes M0245 and Q0245 are authorized for administration together under an Emergency Use Authorization (EUA) by the FDA for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARSCoV-2 viral testing and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Modifiers SA, SB, UD, U7 and 99 are allowed.

#### **Limitations of Authorized Use**

Bamlanivimab and etesevimab are not authorized for use in patients who are hospitalized for COVID-19, or require oxygen therapy due to COVID-19, or require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity. Treatment with bamlanivimab and etesevimab has not been studied in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab and etesevimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

#### **Patient Selection**

Bamlanivimab and etesevimab should be administered together as soon as possible after positive viral test for SARS-CoV-2 and within 10 days of symptom onset in adults and pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progressing to severe COVID-19 and/or hospitalization. High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) 35 or higher
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are 65 years of age or older
- Are 55 years of age or older and have one of the following:
  - cardiovascular disease
  - hypertension
  - chronic obstructive pulmonary disease/other chronic respiratory disease
- Are 12 to 17 years of age and have one of the following:
  - BMI in the 85th percentile or higher for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical\_charts.htm
  - sickle cell disease
  - congenital or acquired heart disease
  - neurodevelopmental disorders (for example, cerebral palsy)
  - a medical-related technological dependence (for example, tracheostomy, gastrostomy or positive pressure ventilation not related to COVID-19)
  - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control

#### Dosage

The dosage of bamlanivimab and etesevimab for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) is:

- Bamlanivimab 700 mg
- Etesevimab 1,400 mg

Administer bamlanivimab and etesevimab together as soon as possible after positive viral test for SARS-CoV-2 and within 10 days of symptom onset. Under this EUA, bamlanivimab and etesevimab must be diluted and administered together as a single intravenous infusion.

Bamlanivimab and etesevimab solution for infusion should be prepared by a qualified healthcare professional. For additional details on dose preparation, administration, storage, warnings and precautions, see <u>Fact Sheet for Health Care Providers</u>.

## **Patient Monitoring Recommendations**

Clinically monitor patients during administration and observe patients for at least 1 hour after infusion is complete.

For "Mandatory Requirements for Bamlanivimab and Etesevimab Administration Under EUA" and "Instructions for Healthcare Providers," submission of adverse events reports, please see the Fact Sheet for Health Care Providers.

#### Instructions for Healthcare Providers

As the healthcare provider, you must communicate to your patient or parent/caregiver, as age appropriate, information consistent with the "<u>Fact Sheet for Patients, Parents and Caregivers</u>" (and provide a copy of the Fact Sheet) prior to the patient receiving bamlanivimab and etesevimab as instructed.

## **Billing Instructions**

Providers should note the following:

- The Department of Health Care Services (DHCS) will follow CMS guidelines for the reimbursement of bamlanivimab and etesevimab when administered in accordance with FDA EUA.
- Since the initial supply of bamlanivimab and etesevimab is purchased by the federal government and distributed free to providers, providers must not bill Q0245 for the cost of bamlanivimab and etesevimab. DHCS will provide future guidance for the billing and reimbursement of provider purchased products.
- DHCS will reimburse for the cost of administration (infusion) when billed with the administration code, M0245.
- In accordance with CMS guidelines, providers must maintain appropriate medical
  documentation that supports the medical necessity of the service, including
  documentation that supports that the terms of the EUAs are met. The documentation
  should also include the name of the provider who ordered or made the decision to
  administer the infusion.
- It is important to provide monoclonal antibody recipients an EUA fact sheet for patients/caregivers for the applicable product.

## Injections

Effective for dates of service on or after April 1, 2021, the following injection codes have special billing policy:

C9074, J1427, J1554

#### C9074

HCPCS code C9074 is a HAO1-directed small interfering ribonucleic acid (siRNA) indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult. The following ICD-10-CM diagnosis code is required on the claim: E72.53. Providers must submit an invoice showing the acquisition cost of the product in addition to the product National Drug Code (NDC) for reimbursement.

Frequency of billing = every 28 days.

The recommended dose is based on body weight.

## **Dosage Based on Body Weight Table**

Body Weight	Loading Dose	Maintenance Dose (begin one month after the last loading dose)
Less than 10 kg	6 mg/kg once monthly for 3 doses	3 mg/kg once monthly
10 kg to less than 20 kg	6 mg/kg once monthly for 3 doses	6 mg/kg once every 3 months (quarterly)
20 kg and above	3 mg/kg once monthly for 3 doses	3 mg/kg once every 3 months (quarterly)

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include clinical documentation that demonstrates all of the following:

- Must be for FDA-approved indications and dosages
- Must be prescribed by, or in consultation with, a nephrologist, endocrinologist, or other healthcare provider who is specialized in treating primary hyperoxaluria type 1 (PH1)
- Patient has a diagnosis of PH1 confirmed with one of the following:
  - Genetic testing confirmation of mutation of Alanine glyoxylate aminotransferase (AGXT)
  - Liver biopsy demonstrating decreased or absent activity of alanine:glyoxylate aminotransferase (AGT) for type 1 disease; and
- Patient has at least one of the following:
  - Elevated urinary oxalate excretion persistently greater than 0.7 mmol/1.73 m2/day or above the upper limit of normal (ULN) for age
  - Urinary oxalate-to-creatinine ratio is greater than ULN for age in two of three single-void collections.

- Elevated urinary glycolic acid (glycolate) concentration
- Patient has tried and failed at least three months of pyridoxine (vitamin B6) at up to the maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
- Patient has not had a kidney or liver transplant
- Patient does not have a history of extrarenal systemic oxalosis

Initial approval is for six months

#### Reauthorization

- Patient continues to meet the initial approval criteria
- Patient has experienced clinical benefit as evidenced by reduction in signs and symptoms of PH1 with lumasiran treatment
- Patient has shown improvement or normalization of laboratory values such as urinary oxalate excretion from baseline, or the percent change in spot urinary oxalate-tocreatinine ratio from baseline

Reauthorization is for 12 months

Modifiers SA, UD, U7 and 99 are allowed.

#### <u>J1427</u>

HCPCS code J1427 is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients four years of age and older who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.

The following ICD-10-CM diagnosis code is required on the claim: G71.01.

Frequency of billing = 80 mg/kg administered once every seven days.

An approved *Treatment Authorization Request (TAR)* or CCS Program Service Authorization Request (SAR) is required for reimbursement. The TAR/SAR must include clinical documentation that demonstrates all of the following:

- Must be for FDA-approved indications and dosages
- Patient must be 4 years of age or older
- Must be prescribed by, or in consultation with, a neurologist with expertise in the
  treatment of Duchene Muscular Dystrophy (DMD). For CCS patients, must be under
  the supervision and monitoring of a CCS-paneled neurologist or physical medicine and
  rehabilitation specialist who is fellowship trained in neuromuscular medicine at a CCS
  Neuromuscular Medicine Special Care Center, or at a neurology clinic.
- Must have a diagnosis of DMD with mutation amenable to exon 53 skipping as documented by genetic test(s)
- The following are completed as part of the assessment for antisense oligonucleotide therapy:
  - a. Forced Vital Capacity (FVC),

- b. Brooke score.
- c. 6-minute walk test (6MWT), if ambulatory, and
- d. Renal toxicity screening with urinalysis, creatinine/protein ratio or serum cystatin C.
- The FVC is greater than 30 percent predicted <u>or</u> the Brooke score is less than or equal to 5.
- Only one antisense oligonucleotide treatment shall be authorized at a time
- Patient is on a corticosteroid or has documented medical reason not to be on this medication.
- Patient must start on the less expensive equivalent or superior drug
- Continuation of a more expensive alternative must be justified with a compelling reason for doing so
- For CCS patients, CCS Neuromuscular Medicine SCC or CCS-paneled neurologist has included the following supporting documentation in the medical record:
  - a. Documentation of recent FVC
  - b. Brooke Score or baseline 6MWT if ambulatory
  - c. Laboratory indicator of renal function

Initial Approval is for 12 months

#### Reauthorization

- Patient has finished the initial course and has not had significant decline in FVC beyond the pre-treatment disease trajectory while on the antisense oligonucleotide treatment.
- Motor function has improved or has not declined beyond pretreatment trajectory, evidenced by improved or maintained score in 6MWT, timed function tests, Performance of Upper Limb (PUL), Brooke score, other standardized assessment of motor function, or quantifiable description of improvement by the physician or physical therapist in the medical record.
- Patient has not experienced significant adverse effects attributable to viltolarsen.
- Patients with an FVC score of less than or equal to 30 percent and Brooke score of six will not be granted authorizations because, at the time of this policy, there is insufficient evidence of efficacy in that population.

## Additional consideration for medical necessity determination:

For CCS patients who do not meet the criteria described above, SCCs may also submit other clinical documentation and/or evidence that would support the medical necessity for initial or reauthorization of the patient's antisense oligonucleotide treatments. SCCs should submit this documentation to the Integrated Systems of Care Division (ISCD) Medical Director or designee

Reauthorization is for 12 months.

## **Policy Implementation for CCS Patients**

- A. Submissions of authorization requests for eteplirsen, golodirsen, or viltolarsen are not included in Service Code Groupings. Until the transition of pharmacy benefits to Medi-Cal Rx, providers should submit a separate SAR with the following documentation: a copy of the prescription, genetic laboratory test result with specific mutation, and clinical progress notes from a visit within the past six months.
  - For clients residing in an independent county, SARs should be submitted to the CCS independent county office, which shall review and authorize according to the policy above.
  - For clients residing in a dependent county, SARs should be submitted to the CCS dependent county office. The dependent county program office shall pend and submit the SAR and supporting documentation to the Department of Health Care Services (DHCS) ISCD Special Populations Authorization Unit email at CCSExpeditedReview@dhcs.ca.gov or via secure RightFax (916) 440-5306
- B. All antisense oligonucleotide requests shall be reviewed by a CCS Program Medical Director or designee before authorization.

If you have any questions regarding the policy for CCS patients, please contact the ISCD Medical Director or designee, via e-mail at <a href="mailto:ISCD-MedicalPolicy@dhcs.ca.gov">ISCD-MedicalPolicy@dhcs.ca.gov</a>.

After the transition of pharmacy benefits to Medi-Cal Rx in 2021, all requests for prior authorization of medications billed by National Drug Code and dispensed by a Medi-Cal enrolled pharmacy provider, shall be sent from the pharmacy provider to the Medi-Cal Rx vendor, Magellan Medicaid Administration, Inc. (Magellan). The Medi-Cal RX website provides guidance:

https://medi-calrx.dhcs.ca.gov/home/.

Modifiers UD and 99 are allowed.

#### J1554

HCPCS code J1554 is a 10% immune globulin liquid for intravenous injection, indicated for the treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12 to 17 years of age).

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. TARs may be approved for any of the FDA-approved indications. In many instances, immune globulin is not considered first line therapy and may be used as second line therapy or in special circumstances. The TAR must not only state the diagnoses but also must contain sufficient clinical information to establish medical necessity.

Modifiers SA, UD, U7 and 99 are allowed.

## Non-Injectable Drugs

Effective for dates of service on or after April 1, 2021, the following non-injectable drug codes have special billing policy:

#### J7402

HCPCS code J7402 is a corticosteroid-eluting (mometasone furoate) sinus implant indicated for the treatment of nasal polyps in patients 18 years of age and older who have had ethmoid sinus surgery sinus implant.

Frequency = 1350 mcg/135 units each nostril. May repeat one time after 90 days. One repeat in a lifetime.

Maximum dose = 1350 mcg/135 units each nostril

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include clinical documentation that demonstrates all of the following:

- Must be for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Sinuva is prescribed and implanted by or in consultation with an otolaryngologist
- Patient has undergone ethmoid sinus surgery
- Patient has a diagnosis of recurrent nasal polyps and chronic sinusitis
- Patient must have tried and failed inhaled nasal corticosteroids for at least three months at the maximum recommended dosage, unless intolerant to or has a contraindication to it
- Patient does not have a known hypersensitivity to mometasone furoate or any ingredient in Sinuva sinus implant

Initial approval is for 90 days

#### Reauthorization

- For repeat implant placement, patient must have ethmoid sinus polyps grade greater than or equal to 1 on either side
- One time repeat allowable after 90 days if patient meets criteria for repeat placement

## **Propel Sinus Implants**

Billing

HPCS code S1091:

- Effective April 1, 2021, use S1091 to bill Propel sinus implants (Propel, Propel Mini and Propel Contour).
- Providers must submit a TAR justifying medical necessity.
- Provider must include an invoice showing the acquisition cost of the product in addition to the product National Drug Code (NDC) for appropriate reimbursement.

Modifiers UD and 99 are allowed. Modifiers LT and RT are required.

## **Pathology**

The following pathology codes have special billing policy:

0017M, 0242U, 0244U, 0245U, 0246U

## 0017M

Effective for dates of service on or after January 1, 2021, HCPCS code 0017M has a frequency of once in a lifetime.

The following ICD-10-CM codes are required on the claim: C83.30, C83.31, C83.32, C83.33, C83.34, C83.35, C83.36, C83.37, C83.38, C83.39

Modifiers 33, 90, and 99 are allowed

#### 0242U

Effective for dates of service on or after April 1, 2021, HCPCS code 0242U has a frequency of once in a lifetime.

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include clinical documentation that demonstrates all of the following:

- 1. Patient has non-small cell lung cancer
- 2. Treatment is contingent on test result

Modifiers 33, 90 and 99 are allowed.

## 0244U

Effective for dates of service on or after April 1, 2021, HCPCS code 0244U requires an approved *Treatment Authorization Request* (TAR) for reimbursement. The TAR must include clinical documentation that demonstrates all of the following:

## For Somatic Testing:

- The patient has either recurrent, relapsed, refractory, metastatic or advanced stages III or IV cancer, and
- The patient either has not been previously tested using the same Next Generation Sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician, and
- The decision for additional cancer treatment is contingent on the test results.

## For Germline Testing:

- Ovarian or breast cancer; and
- Clinical indication for germline (inherited) testing for hereditary breast or ovarian cancer (for example, American College of Obstetrician and Gynecologists' criteria for further genetic evaluation for hereditary [germline] breast and ovarian cancer) and

- A risk factor for germline (inherited) breast or ovarian cancer; and (BRCAPRO, Myriad, Claus, Boadicea, or Tyrer Cuzick) and
- Has not been previously tested with the same germline test using NGS for the same germline genetic content

Modifiers 33, 90, and 99 are allowed.

## 0245U

Effective for dates of service on or after April 1, 2021, HCPCS code 0245U has a frequency of once in a lifetime.

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include clinical documentation that demonstrates all of the following:

- The patient is under evaluation for thyroid nodule(s)
- The cytopathology result from fine needle aspiration is indeterminate, defined as one of the following:
  - a. Follicular lesion of undetermined significance (FLUS), Bethesda III, or
  - b. Atypia of undetermined significance (AUS), Bethesda III, or
  - c. Follicular neoplasm, Bethesda IV
- The diagnostic or treatment strategy will be contingent on test results

Modifiers 33, 90, and 99 are allowed.

#### 0246U

Effective for dates of service on or after April 1, 2021, HCPCS code 0246U is reimbursable for Presumptive Eligibility for Pregnant Women (PE4PW) services.

Modifiers 33, 90 and 99 are allowed.

## Radiology

Effective for dates of service on or after April 1, 2021, the following radiology code has special billing policy:

#### A9592

HCPCS code A9592 is a radioactive diagnostic agent indicated for use with positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine tumors (NETs) in patients18 years of age and older.

The recommended amount of radioactivity to be administered for PET imaging is 148 MBq (4 mCi) administered as an intravenous injection over a period of approximately one minute. Begin acquiring images 45 to 90 minutes after drug administration.

Maximum billing unit(s)= 4 mCi/ 4 units

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

The TAR must include clinical documentation that demonstrates all of the following:

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient must have an approval for a PET scan and the PET scan code must be billed on the same date of service
- Patient must have at least one of the following:
  - Confirmed or suspicion of neuroendocrine tumor (NET) based on histology/biopsy report.
  - Confirmed or suspicion of NET based on conventional imaging scans of affected area such as MRI and/or contrast enhanced CT and/or an FDG PET/CT scan and/or NaF PET/CT scan and/or OctreoScan<sup>®</sup> and/or clinical symptoms performed within 8 weeks prior to administration of Copper Cu 64 Dotatate.
- Patient must not be a pregnant or breast-feeding female
  - Breast feeding patients to interrupt breastfeeding for 12 hours after Detectnet administration
- Patient does not have either of the following:
  - Therapeutic use of any somatostatin analogue, including Sandostatin<sup>®</sup> LAR and Lanreotide (within 28 days) and Sandostatin (within two days) prior to administration with Copper Cu 64 Dotatate.
  - History or presence of significant hematological abnormalities or immunodeficiency or any condition that might compromise the immune system (infections, vaccinations), of any etiology as indicated by clinically significantly abnormal values of any of the following hematologic parameters: platelets, hemoglobin, WBC count and ANC

Approval is for three months

#### **Billing**

HCPCS code A9592, Copper cu-64, dotatate, diagnostic, 1 millicurie Modifiers SA, UD, U7 and 99 are allowed.

## **Quarter 2 Code Changes**

## **Injections**

## <u>J7321</u>

Effective for dates of service on or after April 1, 2021, HCPCS code J7321 is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (for example, acetaminophen). It is used for billing Supartz, Hyalgan and Visco-3

Hyalgan/supartz/visco-3 now has a maximum dose of 5 doses/5 units for knees.

Frequency = 1 dose weekly for 5 weeks. May repeat after 180 days = 5 doses/5 units every 180 days per knee.

## **Quarter 2 Code Deletions**

# Table of Quarter 2 Code Deletions Effective for Dates of Service on or After April 1, 2021

Department	Deleted Code
Chemotherapy	C9069
	C9070
Injection	C9071
	C9072
	C9073
	C9122
	J7333
Non-Injectable Drugs	J7401
Radiology	C9068
Respiratory	0098U
	0099U
	0100U

## Table of Quarter 2 Code Deletions Effective for Dates of Service on or After January 1, 2021

Department	Deleted Code
Therapy	G2061 G2062
	G2063